SCIENTIFIC COOPERATION (ESCO)

Minutes of the 2nd meeting of the ESCO Working Group on Botanicals and Botanical Preparations

Parma, 18 November 2008

(EFSA-Q-2008-388)

Participants

WG Experts:	Ilze Abolina (LV), Judith Amberg-Müller (CH), Robert Anton (External Expert), Ulla Beckman-Sundh (SE), Angelo Carere (External Expert), Luc Delmulle (External Expert), Birgit Dusemund (DE), Corrado L. Galli (Contam), Yvonne Holm (FI), Marie-Hélène Loulergue (FR), Martijn Martena (NL), Maria Teresa Nogueira (PT), Kirsten Pilegaard (External Expert), Ivonne Rietjens (ANS), Mauro Serafini (IT), Vittorio Silano (chair, Scientific Committee), Gerrit Speijers (ANS), Jaroslav Toth (SK) and Magdalini Zika (GR).
EFSA:	Bernard Bottex, Djien LIEM (SCAF)

1. Welcome and apologies

The Chair welcomed the participants to this mid-term review meeting of the ESCO Working Group on Botanicals.

Apologies were received from Andrew Chesson (FEEDAP), Andrea Lugasi (HU), Arnold Vlietinck (BE), Jacqueline Koch (EMEA HMPC) and Fabio d'Atri (EC-DG Sanco).

2. Adoption of agenda

The order of the agenda was slightly modified with the decision to look at the Compendium before reviewing the examples used to test the draft framework.

The agenda was adopted as modified.

3. Declarations of interest

The members of the Working Group had no additional interest other than the ones listed in their annual DoI to declare.

4. Discussions

The participants were updated about the outcome of the public consultation on the draft guidance for the safety assessment of botanicals and botanical preparations and the compendia. A key topic section has been created on the EFSA website where the updated guidance document, a report explaining how the comments received were taken into account

by the SC Working Group on Botanicals and the mandate given to this ESCO Working Group can be downloaded:
HTTP://WWW.EFSA.EUROPA.EU/EFSA/KEYTOPICS/EFSA_LOCALE-1178620753812_BOTANICALS.HTM

The participants were also briefly presented the ongoing NDA activities on claims. About 1/3 of the claims are related to botanical preparations. The draft guidance document on the safety assessment of botanicals and botanical preparations was considered by the NDA Panel when agreeing on the data needed to conclude that a botanical preparation is adequately characterised.

The Chair of the Subgroups on Compendium and Real Cases summarised the work done so far.

The following meeting dates and locations have been planned in order to finalise the ESCO activity:

- Plenary meeting:

24 March 2009 (Parma)

- Subgroup Real Cases:

12 February 2009 (Amsterdam)

- Subgroup Compendium

13 February 2009 (Amsterdam)
25 March 2009 (Parma)

Members of the ESCO Working group are invited to block the relevant dates in their agendas.